Remarks

A. Pending Claims

Claims 1-14, 19-27, and 35-38 are currently pending. Claims 1, 4-9, 19, 22-27, and 35 have been amended. Claim 38 is new.

B. In the Drawings

Applicant respectfully requests that the accompanying amended drawing (Fig. 3) be approved by the Examiner in the above-identified application. The distal end of the proximal portion of sleeve member 40 has been "opened" up. Element number 40 for the proximal portion of catheter 10 has been moved to better agree with element number 40 for the distal portion of catheter 10.

C. Comments on Election/Restrictions

The Examiner stated, "The Examiner is not in agreement that all the independent claims are generic to all the species. See figs. 7 a-c. There is no collapsible lumen in all the embodiments." Applicant respectfully disagrees. The Applicant discloses in Figs. 7a-c and in the specification collapsible lumens 702, 724, and 722.

D. Objections to Information Disclosure Statement

The Examiner rejected part of the information disclosure statement received February 5, 2001, on the grounds that portions of copies of foreign and/or publications were illegible. The

Examiner marked page 7 of 7 (references GA-GN) as not considered. Applicant will resubmit the unconsidered art (references GA-GN) along with new art to be considered.

E. Objections to Drawings

The Examiner objected to Fig. 3 stating that the figure is unclear. Applicant submits herewith in an accompanying document an amended Fig. 3 drawing.

The Examiner objected to reference number "726" as not being supported in the specification. Applicant respectfully disagrees with this objection. Applicant submits that support for reference number "726" may be at least found in the specification on page 22, lines 8-9, "In this embodiment the distal end 726 has a reduced end opening or no opening at all." Applicant respectfully requests removal of the objection.

The Examiner objected to the drawings as unclear stating, "It is unclear in the drawings what the hollow support member is. There is no element number shown." Applicant respectfully disagrees with the objection. At least one embodiment of the hollow support member is supported in the drawings and the specification as "reinforced section 704"

F. Objections to Specification

The Examiner objected to the specification under 37 CFR 1.71 because of a lack of enablement as shown in Fig. 3. Applicant has submitted a proposed amendment to Fig. 3 in an accompanying document.

The Examiner objected to the specification under 37 CFR 1.75(d)(1) for failing to provide proper antecedent basis for the claimed subject matter. The Examiner states, "There is no

support for the collapsible lumen to be collapsed inside the catheter body. (see claims 2, 20) It is the Examiner's interpretation that the lumen is collapsed onto the catheter body." Applicant respectfully disagrees with the objection.

Applicant submits there is proper support in the specification for claims 2 and 20. Support for claims 2 and 20 can be found in the specification at least on page 6, lines 6-9:

> The collapsible lumen may be folded inside the catheter body or rolled up near the distal end of the catheter. Once the catheter is connected to a heart lung machine, the fluid flow from the machine expands the catheter to its full width and diameter.

The Examiner requested the status of the patent to which applicant is claiming a priority be updated. Applicant has amended the specification to reflect the current status of the patent to which applicant is claiming priority.

G. The Claims Are Not Indefinite Pursuant To 35 U.S.C. § 112 Second Paragraph

The Examiner rejected claims 4, 7, 8-9, and 21-27 under 35 U.S.C. 112 second paragraph as being indefinite. Applicant has amended claims 4, 7, 8-9, and 21-27 for clarification.

H. The Claims Are Not Anticipated By Macoviak Pursuant To 35 U.S.C. § 102(b)

The Examiner rejected claims 1-13, 19-27, 35, and 37 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,738,649 to Macoviak ("Macoviak"). Applicant respectfully disagrees with these rejections.

Amended claim 1 describes a combination of features including: "at least one collapsible

lumen having a proximal and distal end, wherein the distal end is coupled to the catheter body." Amended claim 19 describes a combination of features including: "A device for diffusing the flow of fluids from a medical catheter comprising a longitudinal expandable lumen." Amended claim 35 describes a combination of features including: "a collapsible lumen having a distal and proximal end, wherein the proximal end of the lumen is coupled to the distal end of the support member." At least the above-quoted features of the claims, in combination with other features of the claims, do not appear to be taught or suggested by the cited art.

Macoviak discloses in column 3, lines 7-10:

> (e) the ability to isolate subcirculation regions by selectively inflating the compartmentalizing expandable members to isolate sub-circulations such as the coronary, cerebral, pulmonary, neck and limb sub-circulations.

In addition, Macoviak discloses in column 4, lines 21-33:

> The catheter may have at least one or two major lumen channels. The major channel is a lumen large enough to carry blood and/or robotic instruments used for surgery and for visualization or other investigatory instrumentation. Minor lumen are used for expandable or inflatable members. They may also be used where smaller lumen are desired such as for cardioplegia. Although the catheter shaft may be provided with a single inflatable lumen, it is preferred to provide separate inflatable lumen for each expandable member so that their inflation and deflation can be controlled separately. The diameter of the catheter will vary depending upon the task to be performed and the size of the individual, usually about 5 mm to about 35 mm in outside diameter.

Macoviak discloses in column 5, lines 55-60:

> 1. The distal end. The catheters described here preferably have a distal floppy tip constructed of soft and flexible (floppy), non-kinking, reinforcement ringed, fenestrated, non-thrombogenic, thin-walled, durable synthetic material.

> The distal tip has at least one fenestration to allow passage of robotic intracardiac surgerical devices.

Macoviak discloses in column 6, lines 38-44:

> In the certain embodiments of the double channel design, the two channels can slide independently from each other to optimize positioning of one relative to the other.
>
> In the non-sliding double channel embodiments, an especially ultra-thin wall will exist between the inner and outer lumen, to maximize lumen diameters, yet be strong by virtue of its flat shape supported by the outer walls of the catheter.

Macoviak discloses in column 10, lines 31-40:

> FIG. 5 shows a cross-section of the double major channel and multiple minor lumen construction taken at the point indicated in FIG. 1. The major channel (22) allows for placement of robotic instruments and has an outer thin wall which separates it from another major, but smaller channel (20). Minor lumen (19) and channel (20) permit the inflow and outflow of fluids as required for the particular surgery and minor lumens (60) permit the fluid connection for inflation of the expandable members. The minor lumens are used as non-robotic perfusion lumens.

Macoviak appears to teach one or more minor lumens (60) for inflating expandable members. For this reason Macoviak appears to refer to lumens (60) as inflatable lumens merely because lumens (60) are used for inflating expandable members and lumens (60) are not themselves collapsible. Macoviak appears to teach non-collapsible major channels (20) and (22) separated by a thin wall supported by the outer walls of the catheter. Macoviak appears to teach a floppy tip that is non-kinking and reinforcement ringed. Macoviak does not appear to teach or suggest a collapsible lumen and/or longitudinally expandable lumen. Applicant submits that the combination of features in claims 1, 19, and 35 and the claims dependent thereon are neither taught nor suggested by the cited art. Applicant respectfully requests removal of the rejection of

claims 1, 19, and 35 and claims dependent thereon.

Applicant believes many of the claims dependent on claims 1, 19, and 35 may be separately patentable. For example, amended claims 2 and 20 recite, in part: "wherein the lumen is adaptable to be collapsed inside the catheter body." At least the above-quoted feature of the claim, in combination with other features of the claim, does not appear to be taught or suggested by the cited art.

Amended claims 7 and 25 recites, in part: "wherein the nozzle is tapered." At least the above-quoted feature of the claims, in combination with other features of the claims, does not appear to be taught or suggested by the cited art.

Claim 11 recites, in part: "wherein the support member comprises a tubular member and a coil, and the coil is disposed within the tubular member." At least the above-quoted features of the claim, in combination with other features of the claim, do not appear to be taught or suggested by the cited art.

I. The Claims Are Not Anticipated By Abiuso Pursuant To 35 U.S.C. § 102(b)

The Examiner rejected claims 1-2, 4-6, 12, 13, 19, 20, 22-23, and 35-36 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,213,576 to Abiuso et al. ("Abiuso"). Applicant respectfully disagrees with these rejections.

In the Office Action, the Examiner states:

> Abiuso et al. disclose a catheter having a catheter body, at least one collapsible lumen (balloon 26 or 28). The balloon member/dilator is considered the second balloon (26 or 28).

Amended claim 1 describes a combination of features including: "an opening located on the distal end of the collapsible lumen." Amended claim 19 describes a combination of features including: "an opening located on a distal end of the longitudinal expandable lumen." Amended claim 35 describes a combination of features including: "a hollow support member coupled to the catheter body having a distal and proximal end, wherein the proximal end of the support member is coupled to the distal end of the catheter body." At least the above-quoted feature of the claims, in combination with other features of the claims, does not appear to be taught or suggested by the cited art.

Abiuso discloses in column 4, lines 30-37:

> First and second balloons 26, 28 may be sealed together and to catheter shaft 14 in a common, annular seal 31, which may be a radio frequency heat seal or any other desired seal. At the other end of the respective balloons 26, 28, annular seals 33, 35 of similar nature may be provided between the ends of the balloons and catheter shaft 14, since inner balloon 26 is typically shorter than outer balloon 28

Abiuso appears to teach balloons 26, 28 sealed together and to catheter shaft 14 as shown in Figs. 4, 6, and 8. Abiuso does not appear to teach or suggest an opening located on the distal end of the lumen and/or a hollow support member. Applicant submits that the combination of features in claims 1, 19, 35 and the claims dependent thereon are neither taught nor suggested by the cited art. Applicant respectfully requests removal of the rejection of claims 1, 19, 35, and claims dependent thereon.

Applicant believes many of the claims dependent on claims 1, 19, and 35 may be separately patentable. For example, amended claims 2 and 20 recite, in part: "wherein the lumen is adaptable to be collapsed inside the catheter body." At least the above-quoted feature of the

claim, in combination with other features of the claim, does not appear to be taught or suggested by the cited art.

Claim 36 recites, in part: "wherein the lumen has a diameter which decreases from the proximal end to the distal end." At least the above-quoted features of the claim, in combination with other features of the claim, do not appear to be taught or suggested by the cited art.

J. Double Patenting Rejection

The Examiner rejected claims 1-14 and 19-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,179,827. Applicant respectfully disagrees that the rejection is appropriate. Upon the present application being in condition for allowance but for the provisional double patenting rejection, Applicant will provide arguments for the inappropriateness of the double patenting rejection and/or provide a terminal disclaimer for the patent.

K. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

Applicant believes that no fees are due in association with the filing of this and accompanying documents. If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any fees are required, please charge those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5838-00400/EBM.

Respectfully submitted,

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Date: 6-11-03